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09/842,166	04/26/2001	Edward W. Merrill	37697-0035	7738

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EXAMINER	
MILLER, CHERYL L	
ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 06/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/842,166

Applicant(s)

MERRILL ET AL.

Examiner

Cheryl L. Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 124-149 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 124-149 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Specification*

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Line 3 of the abstract still contains the language "is disclosed." It is suggested to delete noted language.

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 131, 137, and 139, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 139 seems to contain a spelling error in line 1. It is suggested to change "across-linked" to recite --a cross-linked--.

5. Claim 131 recites the limitation "The prosthesis of claim 124" in line 1. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change "The prosthesis of claim 124" to recite --The medical prosthesis of claim 124--.

6. Claim 137 recites the limitation "said heated" in line 5. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change "said heated" to recite --said irradiated--.

*Claim Rejections - 35 USC § 102*

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 139-141 and 147-149 are rejected under 35 U.S.C. 102(e) as being anticipated by Hyon et al (U.S. Patent 6,168,626). Hyon discloses a method for making a cross-linked UHMWPE, which includes all limitations recited in the claims. Referring to claims 139 through 141, Hyon discloses a method of cross-linking UHMWPE comprising the steps of providing UHMWPE at room temperature or below as claimed in 139 (col.3, line 44), at a temperature no more than 90C as claimed in 140 (col.3, lines 44-46), at a temperature of 90C to below the melting point as claimed in 141 (col.3, lines 45-46), irradiating UHMWPE (col.3, lines 32-67), and cooling UHMWPE (col.4, lines 45-55). The heat generated (by irradiation at the provided temperatures listed in col.3, lines 44-46) is sufficient to cross-link and at least partially melt the UHMWPE (col.3, lines 47-65; col.4, lines 4-16).

Referring to claim 147, Hyon discloses a method for making a cross-linked polyethylene comprising the steps providing polyethylene at a temperature below the melting point (col.3, lines 44-46),

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irradiating to cross-link and generate heat to at least partially melt polyethylene (col.3, lines 32-67), and cooling the polyethylene (col.4, lines 44-55).

Referring to claim 148, Hyon discloses an irradiation temperature, which would melt the polyethylene (col.3, lines 39-65).

Referring to claim 149, Hyon discloses further heating the polyethylene (col.4, lines 4-16, 57-60).

***Claim Rejections - 35 USC § 103***

Claims 124, 126-127, 129, 132, and 134-135 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hyon et al (U.S. Patent 6,168,626 B1) in view of Howard, Jr. et al. (U.S. Patent 5,684,124). Hyon discloses the invention substantially as claimed. Referring to claim 124, Hyon discloses a medical prosthesis for use in the body (artificial joint and other medical uses, col.7, lines 51-59) made of ultra high molecular weight polyethylene (UHMWPE, col.2, lines 42-46). Hyon discloses a UHMWPE that has been cross-linked by radiation (col.2, lines 46-55; col.3, lines 32-67) as claimed in 124 and 132. Hyon discloses a UHMWPE, which is subjected to heating by irradiation (col.3, lines 40-46) as claimed in 127 and 135.

Hyon discloses a UHMWPE with a molecular weight greater than 1 million (col.3, lines 21-23) as claimed in 129.

Hyon discloses a UHMWPE having most of the limitation in the claims. However, Hyon does not disclose multiple distinct melting peaks of UHMWPE. Howard teaches in the same field of endeavor, a UHMWPE medical prosthesis (col.1, lines 21-29), which has multiple melting peaks (col.3, lines 29-36), specifically two melting peaks, as claimed in 126 and 134, which is a property of the UHMWPE material that is manipulated for the purpose of improving mechanical properties such as crystallinity. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Howard's teaching of UHMWPE melting peak manipulation, with Hyon's UHMWPE medical prosthesis, in order to optimize the desired mechanical properties of the polymer.

Referring to claim 130, Hyon discloses a UHMWPE medical prosthesis for replacing a joint selected from the group consisting of hip, knee, elbow, shoulder, ankle, and finger (col.1, lines 25-28; col.2, lines 42-46; col.7, lines 45-56).

9. Claim 125 and 133 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hyon et al. in view of Howard Jr. et al. as applied to claim 124 and 132 respectively above, and further in view of Bashir et al. (U.S. Patent 5,001,206). Hyon in view of Howard disclose an UHMWPE with multiple melting peaks substantially as claimed. Hyon in view of Howard does not disclose however, a UHMWPE with three melting peaks. Bashir teaches in the analogous art of polymers, a polyethylene polymer (col.2, lines 60- col.3, lines 2; col.3, lines 23-24; col.4, lines 34-40) having 3 melting peaks (col.6, lines 23-45) in order to optimize mechanical properties. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Bashir's teaching of UHMWPE melting peak manipulation, with Hyon in view of Howard's UHMWPE medical prosthesis in order to further optimize the desired mechanical properties of the polymer implant.

10. Claim 128 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hyon in view of Howard as applied to claim 124 above, and further in view of Dearnaley et al. (U.S. Patent 5,593,719). Hyon in view of Howard disclose the invention substantially as claimed. However, neither disclose use of xylene or DECALIN. Dearnaley teaches in the same field of endeavor a UHMWPE which is subjected to DECALIN or xylene (col.4, lines 21-31) at temperatures similar to as claimed for 24 hours before the solvent is removed (col.4, lines 32-64; col.8, lines 58-65) for the purpose of selective dissolution of any small, low molecular weight particles, without damaging high molecular weight polymer chains (col.8, lines 63-65), thus non-dissolved high molecular weight UHMWPE shows optimal strength and mechanical properties. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Dearnaley's teaching that dissolution in DECALIN or xylene is dependent upon molecular weight, Hyon in view of Howard's ultra high molecular weight polyethylene

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in order to provide a polyethylene with a molecular weight high enough and reduced small chains to optimize the desired mechanical properties.

11. Claim 131 and 136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hyon in view of Howard as applied to claim 124 and 132 respectively above, and further in view of Parikh et al. (U.S. Patent 6,005,053). Hyon in view of Howard disclose the invention substantially as claimed. Hyon discloses the importance of optimizing properties such as tensile modulus less than 940 Mpa and crystallinity to match the properties of the materials surrounding the prosthesis (col.3, lines 12-16, 33-39; col.7-col.8; table 2). Howard also discloses importance of tensile modulus and crystallinity also. Parikh teaches in the analogous field of polymers a polyethylene polymer, which has a crystallinity of less than 50 percent (col.2, lines 1-4) and a tensile modulus below 940 Mpa (col.42, line 15) for the purpose of optimal mechanical properties. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a polyethylene polymer with values of crystallinity and tensile modulus as disclosed by Parikh, for a medical prosthesis with optimal tensile and crystalline properties as disclosed by Hyon in view of Howard, in order to create an implant with optimal properties similar to the surrounding tissues.

12. Claims 137 and 138 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al. (U.S. Patent 6,174,934) in view of Howard et al. (U.S. Patent 5,684,124). Sun discloses the invention substantially as claimed. Referring to claim 137, Sun discloses a method for making a UHMWPE (col.1, lines 16-20) comprising the steps of providing UHMWPE, irradiating to cross-link (col.4, lines 39-43), and cooling UHMWPE (col.5, line 67-col.6, line 1). Referring to claim 138, Sun discloses providing UHMWPE at a temperature between room temperature and the melting point of the polymer (col.5, lines 55-57). Sun does not disclose however, a UHMWPE, which has multiple melting peaks. Howard teaches in the same field of endeavor, a UHMWPE, which has multiple melting peaks that are manipulated to optimize material properties (col.2, lines 36-37; col.19, lines 1-4). It would have been obvious to one

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having ordinary skill in the art at the time the invention was made to combine Howard's teaching of melting peak manipulation of a UHMWPE, with the method of treating UHMWPE as disclosed by Sun in order to optimize mechanical properties.

13. Claim 142 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al. (U.S. Patent 6,174,934) in view of Rose et al. (Radiation Sterilization and the Wear Rate of Polyethylene). Sun discloses the invention substantially as claimed. Sun discloses a method of cross-linking UHMWPE to eliminate free radicals (col.5, lines 28-39). Said method is completed by irradiation, and heating at a temperature below the melting point of UHMWPE (col.5, lines 55-37), followed by a cooling step (col.5, line 67-col.6, line1). Sun however, discloses an irradiation dose of 2.5 Mrads (col.7, lines53-55), lower than the dose claimed. Rose teaches in the same field of endeavor, irradiation of UHMWPE in doses above 5 Mrads (p.394, col.2; p.396; Figure3) improves cross-linking without increasing wear. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a high irradiation dose as disclosed by Rose, to method of treating UHMWPE as disclosed by Sun in order to reduce wear of UHMWPE.

14. Claim 143 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al. (USPN 6,174,934) in view of Rose et al. (Radiation Sterilization and the Wear Rate of Polyethylene) as applied to claim 142 above, and further in view of Hyon et al. (U.S. Patent 6,168,626). Sun in view of Rose disclose the invention substantially as claimed. However, they do not disclose irradiation at a temperature above the melting point of UHMWPE. Hyon teaches in the same field of endeavor a method of cross-linking UHMWPE (col.2, lines 47-55; col.3, lines 62-65) as claimed, which uses a temperature above the melting point of the polymer (col.4, lines4-12). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the method of cross-linking as disclosed by Sun in view of Rose, with temperatures disclosed by Hyon in order to partially melt the polymer.



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15. Claim 144 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dearnaley et al. (U.S. Patent 5,593,719) in view of Howard, Jr. et al. (U.S. Patent 5,684,124). Dearnaley discloses the invention substantially as claimed. Dearnaley discloses a method to make a medical prosthesis made of UHMWPE (col.4, lines 12-17; col.1, lines 21-22, 29-31) as claimed. Said method reduced particles produced during wear (col.3, lines 46-60) by radiation (col.4, lines 61-64; col.7, lines 58-64). Said method is disclosed to produce a load-bearing surface (col.3, lines 48-49) as claimed. Dearnaley however, is silent to mention the number of melting peaks associated with the UHMWPE used. Howard teaches in the same field of endeavor, a method of making a UHMWPE used as a load bearing surface in the body (col.1, lines 22-29), and manipulates the multiple melting peaks (col.2, lines 36-37; col.19, lines 1-4) in order to optimize mechanical properties such as crystallinity and tensile modulus. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Howard's teaching of melting peak manipulation of UHMWPE, with a method to reduce particles of wear in a UHMWPE such as disclosed by Dearnaley to further optimize mechanical properties of a UHMWPE prosthesis.

16. Claims 145 and 146 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dearnaley et al. (U.S. Patent 5,593,719) in view of Rose et al. (Radiation Sterilization and the Wear Rate of Polyethylene). Dearnaley discloses the invention substantially as claimed. Dearnaley discloses a method of making a medical prosthesis made of UHMWPE (col.4, lines 12-17; col.1, lines 21-22, 29-31) as claimed. Said method was disclosed to reduce particles produced during wear (col.3, lines 46-60) by radiation (col.4, lines 61-64; col.7, lines 58-64) at a temperature above room temperature (col.4, lines 32-39). Said method is disclosed to produce a load-bearing surface (col.3, lines 48-49) as claimed.

Dearnaley however, is silent to mention an irradiation dose applied to the UHMWPE. Rose teaches in the same field of endeavor, an irradiation dose treatment of above 2 and 4 Mrads (p.394, col.1; p.394, col.2) as claimed in 145 and 146 respectively, for the same purpose of reducing wear, thus particle production. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use

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a method of making UHMWPE as disclosed by Dearnaley and choosing an irradiation technique similar to what is disclosed by Rose in order to have reduced particle production and wear.

*Response to Arguments*

17. Applicant's arguments filed April 16, 2002 have been fully considered but they are not persuasive. It is first noted that applicant used open terminology in the claims "comprising", meaning the claims are not limited to the limitations recited in the claims. If applicant wishes to claim a method *only* containing the steps claimed (as applicant points out in arguments), without additional steps, applicant is advised to use closed terminology such as --consisting-- or --including--.

Applicant's argument against the Hyon reference (USPN 6,168,626) was non-persuasive. Hyon does indeed disclose providing UHMWPE at a temperature near room temperature, or higher, or a temperature not less than 80°C (col.3, lines 40-46). The following column (col.4) discloses that melting occurs at such temperatures. Also, Hyon discloses irradiation being preformed at a dose similar to irradiation doses disclosed in applicant's specification, therefore it is inherent that the heat generated will be the same.

Applicant's argument against the Howard reference (USPN 5,684,124) was non-persuasive. Melting peaks are an inherent property of the material. Howard discloses manipulation of multiple melting peak temperatures. Howard discloses melting peaks similar to melting peaks disclosed in applicant's specification. Also, applicant did not claim generation of multiple melting peaks caused by cross-linking.

Applicant's argument against the Dearnaley reference (USPN 5,593,719) was non-persuasive. Applicant claims a substantial portion of polymer structure will not dissolve in xylene or DECALIN. Dearnaley teaches that submersion of UHMWPE into DECALIN or xylene will dissolve small, low molecular weight chains (non-cross-linked chains), however will not dissolve large, cross linked, high molecular weight chains.

Applicant's argument against the Parikh reference (USPN 6,005,053) was non-persuasive. Applicant claims material properties of a material that are known to be easily manipulated to match the surrounding tissues where the prosthesis is to be implanted.

Applicant's argument against the Sun reference (USPN 6,174,934) and Rose reference were non-persuasive.

18. Applicant's arguments with respect to claim 149 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Conclusion***

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl L. Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

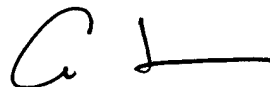
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Cheryl L. Miller

06/21/2002



**CORRINE McDERMOTT  
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